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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ballard Spahr Andrews & Ingersoll, LLP SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER	
			GWARTNEY, ELIZABETH A	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,306	Applicant(s) SCHYMURA, MARTIN
	Examiner Elizabeth Gwartney	Art Unit 1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-32 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 18-32 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 05 June 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20060605</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 22 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 22, the formula recitation " $H_3H_{12}gmNO_{10}$ " renders the claim indefinite.

It is unclear what "gm" in the formula represents. Clarification is requested.

Claim 28 recites the limitation "the substances" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant means at least one of the ingredients from the composition or just one of the substances of the "at least one mixture" of L-carnitine referred to in lines 9-10 of claim 18.

Further, regarding claim 28, the recitation "originates from controlled biological cultivation in accordance with EC regulations" renders the claim indefinite. It is unclear what properties make a substance originate from controlled biological cultivation.

Use Claim

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 provides for the use of a fruit gum, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 32 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 18-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (US 6,077,557) in view of Engel et al. (US 5,976,550) and as evidenced by Food Chemicals Codex ("L-Carnitine", "Carnauba Wax", and "Beeswax, White").

Regarding claims 18 and 20-21, Gordon et al. disclose an intermediate moisture sweetened gelled food, i.e. fruit snacks, composition comprising nutritive carbohydrate sweeteners, gelling agents, acidulants, flavoring, coloring agents (Abstract, C1/L27-28, C6/L49-63, C9/L31-60) and a coating of sugar or oil and wax (C14/L25-46)

While Gordon et al. disclose fruit snacks supplemented with calcium (Abstract), the reference does not disclose that the fruit snacks additionally comprise L-carnitine in pure crystalline form having a degree of purity of 99% and not more than 1% of residual components.

Engel et al. teach a sugar based confectionary containing therapeutic amounts of L-carnitine (Abstract). Engel et al. teach that L-carnitine is a fat metabolizing nutriceutical that helps burn whatever fat the body does consume (C3/L35-41).

As evidenced by Food Chemicals Codex, L-carnitine occurs as white crystals, has the formula weight $C_7H_{15}NO_3$, and has a molecular mass of 161.20 (p.1/Formula, Description). Given that Engel et al. teach L-carnitine, it is clear that the L-carnitine would intrinsically possess the recited properties. Further, given that Engel et al. teach L-carnitine broadly, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any L-carnitine including the pure crystalline form, to arrive at the

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current invention. Further, by using a pure crystalline form, no off-flavors or impurities would be added to the final fruit snack product.

Gordon et al. and Engel et al. are combinable because they are concerned with the same field of endeavor namely, nutritionally supplemented confectionary products. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added L-carnitine, as taught by Engel et al., to the fruit snacks of Gordon et al. for the purpose of metabolizing fat and contributing to weight loss.

Regarding claim 19, modified Gordon et al. disclose all of the claim limitations as set forth above. However, there is no disclosure that the L-carnitine is a crystalline tartrate having the formula $C_{18}H_{36}N_2O_{12}$ and having a molecular mass of 472.49. Given that Engel et al. teach L-carnitine broadly, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any L-carnitine, including crystalline tartrate having the formula $C_{18}H_{36}N_2O_{12}$ and having a molecular mass of 472.49, to arrive at the current invention.

Regarding claim 22, modified Gordon et al. disclose all of the claim limitations including that the fruit snack composition comprises an L-carnitine in a form which is at least sometimes crystalline, having the formula $C_7H_{15}NO_3$. Given that modified Gordon et al. disclose a L-carnitine, the limitations of claim 22 have been met.

Regarding claims 23-25, modified Gordon et al. disclose all of the claim limitations as set forth above. Further, Gordon et al. disclose that the sweetener is selected from the group consisting of sucrose, fructose, or mixtures thereof (C4/L46-57); the gelatinizer comprises

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gelatin, pectin, starch, or mixtures thereof (C6/L49-63); and the souring agent comprises citric acid, malic acid, or mixtures thereof (C10/L4-5).

Regarding claim 26, modified Gordon et al. disclose all of the claim limitations as set forth above. Given that Gordon et al. disclose coloring agents broadly, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any coloring agent, including fruit or plant extract, artificial color or nature-identical colorant, to arrive at the current invention. Further, given that Gordon et al. disclose composition including color, it is clear that the color would intrinsically have to be either one of artificial or nature-identical.

Regarding claim 27, modified Gordon et al. disclose all of the claim limitations as set forth above. Gordon et al. also disclose that the release and glazing agent comprises wax and a liquid oil (C14/L28-32). While Gordon et al. discloses wax, the reference does not explicitly disclose beeswax or carnauba wax. However, as evidenced by Food Chemicals Codex, it was well known to use beeswax and carnauba wax as glazing agents (Function). Given that Gordon et al. disclose wax broadly, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any food wax, including beeswax or carnauba wax, to arrive at the current invention.

Regarding claim 28, modified Gordon et al. disclose all of the claim limitations as set forth above. Given that modified Gordon et al. disclose a composition identical to that presently claimed, it is clear that at least one of the substances of the composition would intrinsically originate from controlled biological cultivation in accordance with EC regulations.

Regarding claim 29 and 31, Gordon et al. disclose a method of making an intermediate moisture sweetened gelled food, i.e. fruit snacks, composition comprising nutritive carbohydrate sweeteners, gelling agents, acidulants, flavoring, coloring agents (Abstract, C1/L27-28, C6/L49-63, C9/L31-60) and a coating of sugar or oil and wax (C14/L25-46)

While Gordon et al. disclose fruit snacks supplemented with calcium (Abstract), the reference does not disclose that L-carnitine in pure crystalline form having a degree of purity of 99% and not more than 1% of residual components is added to the fruit snack composition.

Engel et al. teach a sugar based confectionary containing therapeutic amounts of L-carnitine (Abstract). Engel et al. teach that L-carnitine is a fat metabolizing nutriceutical that helps burn whatever fat the body does consume.

As evidenced by Food Chemicals Codex, L-carnitine occurs as white crystals, has the formula weight $C_7H_{15}NO_3$, and has a molecular mass of 161.20 (p.1/Formula, Description). Given that Engel et al. teach L-carnitine, it is clear that the L-carnitine would intrinsically possess the recited properties. Further, given that Engel et al. teach L-carnitine broadly, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any L-carnitine including the pure crystalline form, to arrive at the current invention.

Gordon et al. and Engel et al. are combinable because they are concerned with the same field of endeavor namely, nutritionally supplemented confectionary products. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added L-carnitine, as taught by Engel et al., to the fruit snacks of Gordon et al. for the purpose of metabolizing fat and contributing to weight loss.

Regarding claim 30, modified Gordon et al. disclose all of the claim limitations as set forth above. However, there is no disclosure that the L-carnitine is a crystalline tartrate having the formula C₁₈H₃₆N₂O₁₂ and having a molecular mass of 472.49. Given that Engel et al. teach L-carnitine broadly, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any L-carnitine or L- carnitine derivative, including crystalline tartrate having the formula C₁₈H₃₆N₂O₁₂ and having a molecular mass of 472.49, to arrive at the current invention.

Regarding claim 32, modified Gordon et al. disclose all of the claim limitations as set forth above. Gordon et al. also disclose a fruit snack supplemented with calcium (i.e. food supplement).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Hamilton et al. (US 6,562,869) teach a gelatin comprising acetyl-L-carnitine, carbohydrate and flavors. Hamilton et al. does not teach a souring agent or a surface treatment.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Thursday; 7:30AM - 5:00PM EST, working alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794